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The attached photocopy is a true copy of the following document:

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A system for catheterization of the urinary bladder
through an artificial or a natural canal in a user.

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BACKGROUND OF THE INVENTION.

The present invention relates to a system for catheterization of the urinary bladder through an artificial or a natural canal in a user.

5 Catheterization may typically be necessary in the case of postoperative urine retention of newly operated patients in a hospital. Another typical use is with patients suffering from severe cases of urinary incontinence as for disabled individuals like para- or
10 tetraplegics who frequently have no control permitting voluntary urination.

Traditionally, such catheterization is carried out by inserting a catheter through the urethra of the patient. The catheter may be left in place for perma-
15 nent catheterization during several hours or days, which is typically the case in elderly and infirm patients, or be retracted after emptying of the bladder, ie. so-called intermittent catheterization (IC).

Intermittent urethral catheterization performed
20 with intervals of eg. 3 to 6 hours reduces the risk of infection of urethra and the bladder significantly as compared to permanent catheterization and has for many users become increasingly common also in daily life situations outside the clinical environment of a
25 hospital, whereby a significantly improved quality of life has been obtained for this group of patients.

However, intermittent catheterization requires a certain degree of dexterity and mobility which implies that self-catheterization is not always possible,
30 especially in women where the urethral orifice may be difficult to locate.

During recent years, suprapubic catheterization (SPC) has been introduced as an alternative to urethral catheterization. In suprapubic catheterization, a canal
35 is made from the surface skin of the abdominal wall of

a user into the bladder under local or general anaesthesia and by means of a pointed hollow introducer or trocar. After penetration of the trocar into the bladder, a catheter is inserted through the canal thus
5 provided, the inner end of said catheter being retained in the bladder by means of eg. an inflatable balloon abutting the inner wall of the bladder after retraction of the trocar. Although many of the disadvantages connected with urethral catheterization, such as eg.
10 urethral cleavage and urethritis, may be overcome by this technique, infection risk is still high as suprapubic catheterization is typically performed as permanent catheterization due to the fact that the canal may close during replacement of the catheter.
15 Furthermore, the fact that the end of the catheter protrudes well into the bladder when using a balloon, which is necessarily placed at a distance from the end in order to allow in-flow of urine, means that the bladder wall may be injured, the more so as the bladder
20 wall often assumes an at least partially collapsed position in which it rests on the end of the catheter.

GB patent No. 2 275 420 discloses a system for suprapubic catheterization of the bladder permitting intermittent catheterization by means of an accessor or
25 sealing member permanently lodged in the artificial canal. The accessor comprises an outer shell formed by two elongate leaves of a bendable plastics material which are hinged together along one edge and having flanges at one end for securing the accessor to the
30 skin surface. A sealing means in the form of a balloon assembly keeps the canal formed in the accessor closed between emptyings but allows insertion of the catheter. Due to the size and material of the accessor, this system may cause discomfort to the user.

35 Another alternative is provided by the so-called

Mitrofanoff principle, by which a suprapubic canal is surgically made by removing parts of a body section, such as the appendix, another part of the intestinal system, eg. a section of the ileum, or any other
5 suitable tubular body tissue, and subsequently attaching one end of the section to the abdominal skin surface whereas the other end penetrates the bladder wall and protrudes into the bladder, the part being attached to the bladder wall at the point of penetra-
10 tion. Obviously, this technique requires surgery under general anaesthesia and implies a loss of bowel or other tissue as well as stitches in the bladder wall.

SUMMARY OF THE INVENTION.

15 It is the object of the present invention to provide a system for catheterization of the urinary bladder, by which intermittent catheterization may be performed by a larger group of users and which alleviates the problems encountered in the prior art systems.

20 This object is met by a system for catheterization of the urinary bladder through an artificial or a natural canal in a user, comprising a catheter adapted to be inserted through the canal, said system being characterized in that an access member is provided,
25 said access member having an outer end and an inner end defining a predetermined length, and being adapted to extend from the outside of the body through said canal and into the bladder, and having at least one cavity extending substantially throughout said predetermined
30 length; and that said access member comprises a hollow tube made from a thin-walled flexible material.

By this design a system is provided which makes intermittent catheterization a feasible alternative to a large number of users which hitherto have been forced
35 to use permanent catheterization. As a consequence, it

is possible to reduce the risk of infection in this group of users. Furthermore, the system comprises an access member which is very comfortable to wear is provided. In relation to the Mitrofanoff principle, the
5 system according to the invention does not necessarily require surgery under general anaesthesia or any loss of body tissue.

During use as a system for suprapubic catheterization, contraction of the detrusor and the abdominal
10 muscles keeps the through-going cavity of the access member closed, so that urine may not penetrate to the outside and consequently that eg. water may not seep into the bladder when the user is washing or bathing. Nevertheless, intermittent catheterization may be
15 carried out without difficulty by inserting the catheter through the canal provided by the hollow tube.

Advantageous embodiments of the invention are the object of the dependent claims.

20 BRIEF DESCRIPTION OF THE DRAWINGS.

In the following the invention will be described in detail with reference to the schematic drawings, in which

Fig. 1 shows a side view of a system according to
25 the invention during catheterization;

Fig. 2 shows a side view of a part of the system of Fig. 1 during use; and

Fig. 3 shows a sectional view of a detail of a system according to another embodiment of the inven-
30 tion.

DETAILED DESCRIPTION OF THE INVENTION.

In Figs. 1 and 2 a system for suprapubic catheterization is shown, in which an access member 1
35 having a cavity forms a canal from the skin surface 2

of the abdominal wall of the user, which in this case is a female, to the urinary bladder 3, said canal extending above the pubic bone 4. The access member 1 is formed as a hollow tube made from a suitable thin-walled flexible material. Examples of such materials are eg. film made from polyethylene, polyurethane, polypropylene or like material, artificial blood vessels, pig guts, Tripsin, or any other material which can meet the demands to the access member, both with respect to physical properties and bio-compatibility. In addition to being flexible and being able to be produced in a small thickness, the material should thus be soft, possess low surface friction, be able to be coated, welded, heat-sealed and/or glued, coated and be hydrophobic. Furthermore, the material should be able to collapse in a radial direction but be stable axially, be rolled up and non-kinking. With respect to the bio-compatibility of the material, it should prevent stenosis and bio-film formation, not form in-growth with tissue and be non-toxic.

The access member 1 has an outer end 1a which may be secured to the skin surface 2 by any suitable means, eg. a medical grade adhesive, and an inner end 1b which protrudes well into the bladder 3, the outer and inner ends 1a, 1b defining a predetermined length. Examples of suitable adhesives are adhesives based on styrene-isoprene-styrene block polymer (SIS), polyisobutylene (PIB), Silicone Tacky Gel and acrylic polymers. In the embodiment shown, the cavity in the access member 1 extends throughout the predetermined length such that a catheter 5 may be inserted through the canal provided by the access member 1 in order to attain the catheterization position as shown in Fig. 1, in which urine flows from the bladder 3 through inlet openings 5a provided at the end of the catheter and out to a

suitable draining means (not shown).

After catheterization, the catheter 5 is retracted from the bladder 3 through the access member 1 which remains seated in the body of the user.

5 As indicated in Fig. 2 the access member 1 assumes, at least partially, a flattened position between catheterizations as a result of the involuntary contraction of the detrusor and abdominal muscles, and of the pressure exerted by the urine collected in the
10 bladder, respectively. Consequently, the canal between the bladder 3 and the outside of the body provided by the cavity in the access member is kept closed such that virtually no urine may penetrate to the outside. Moreover, the closure of the canal implies that liquid
15 such as water will not seep into the bladder when the user for example washes, takes a shower or bathes.

Initial positioning of the access member 1 may take place by first penetrating the abdominal wall and the wall of the bladder 3 by means of a trocar and by
20 subsequently inserting a catheter or other applicator means carrying on its outer side the access member 1.

In order to insert the access member 1 without discomfort to the user, the exterior surface of the access member may be provided with a coating to provide
25 a slippery low-friction surface character. In order to retain the access member safely within the body the coating may be of a temporary character such that the exterior surface after a predetermined period of time loses its low-friction character.

30 Alternatively, application of the access member may take place as shown in Fig. 3, showing a part of an embodiment of the inventive system comprising a catheter 25 and an access member 21. In this embodiment, an inner end 21b of the access member 21 adapted to be
35 positioned at the end of the catheter 25 provided with

urine inlet openings 25a is designed as a cap having openings 21c which allow urine to flow into the catheter 25 through the inlet openings 25a.

The system according to the invention may alternatively be used in urethral catheterization. By using an access member in connection with urethral catheterization, self-catheterization may be performed even by users having a reduced dexterity and mobility as an access member facilitates the operation of finding the urethral orifice, especially in women. In contrast to permanent catheterization the muscles are furthermore allowed to contract and relax. By letting the outer end protrude from the urethral orifice, this end may easily be gripped by the user in order to position the catheter correctly. This operation is thus much facilitated in relation to urethral catheterization without an access member and makes it possible for even eg. sclerosis patients to perform intermittent self-catheterization which in turn implies that this group of patients gains a significantly improved quality of life in relation to use of permanent catheterization.

The invention is not limited to the embodiment shown and described in the above. Several modifications are conceivable within the scope of the appended claims.

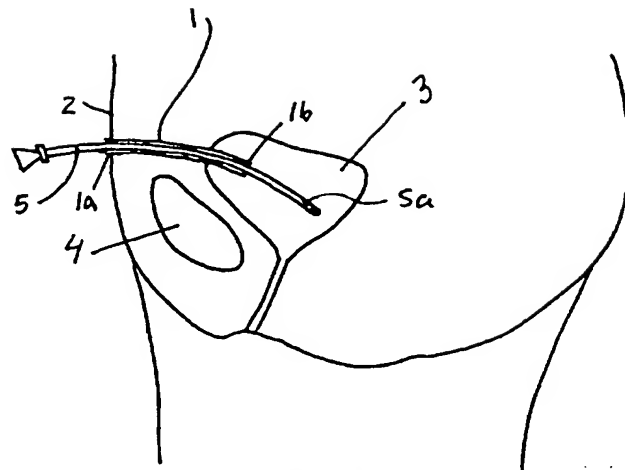


Fig. 1

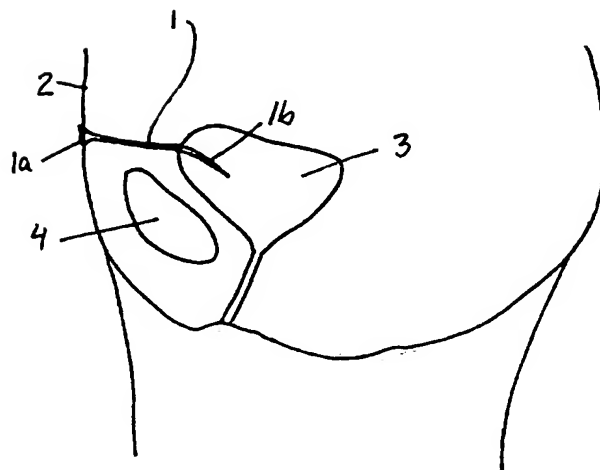


Fig. 2

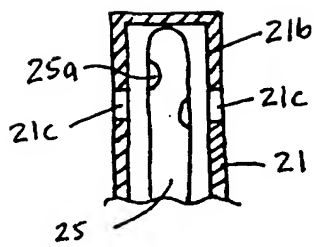


Fig. 3